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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,785	08/01/2001	Paul K. Nakane	266/106	5161

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EXAMINER

LILLING, HERBERT J

ART UNIT PAPER NUMBER

1651

DATE MAILED: 07/11/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/920,785

Applicant(s)

NAKANE, PAUL K.

Examiner

HERBERT J LILLING

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period of Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

1. Claims 1-22 are present in this application.
2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-16 and 21-22, drawn to a method for determining the susceptibility of bacterial cells to an antibiotic, classified in class 435, subclass 32.
 - II. Claims 17-18, drawn to a kit comprising one or more antibiotics, classified in class 424 or 526, numerous subclasses depending upon the antibiotics.
 - III. Claim 19, drawn to a kit comprising one or more antibiotics and a growth medium, classified in class 424 or 526, numerous subclasses depending upon the antibiotic(s).
 - IV. Claim 20, drawn to a kit comprising one or more antibiotics and a fixing agent, classified in class 424 or 526, numerous subclasses depending upon the antibiotic(s).

The inventions are distinct, each from the other because:

Inventions II-IV do not require all of the specifics of Invention I.

Inventions II-IV are patentably distinct from each other. Invention II requires only the antibiotics in the kit.

Art Unit: 1651

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, have acquired a separate status in the art because of their recognized divergent subject matter and the search required for one invention is not required for the other invention, thusly the restriction for examination purposes as indicated is proper.

4. This application contains claims directed to the following patentably distinct species of the claimed invention:

A. Whereby the method comprising susceptibility of bacterial cells to:

- i. one antibiotic;
- ii. a plurality of antibiotics.

B. Whereby the antibiotic is selected from

- a. beta-lactam,
- b. tetracycline,
- c. aminoglycoside,
- d. sulfonamide,
- e. macrolide,
- f. fluoroquinolone,
- g. trimethoprim.

AND a **selection of one of the following** which is within the above elected grouping (a-g) whereby the antibiotic is selected from the group consisting of ampicillin, cefazolin, cephalothin, ceftazidim, gentamycin, mezlocillin, oxacillin, enicillin, piperacillin, ticarcillin and trimthoprim.

C. Whereby the body fluid is selected from the group consisting of:

- 1. serum,

Art Unit: 1651

2. plasma,
3. spinal fluid,
4. phlegm,
5. saliva,
6. nasal discharge,
7. ocular discharge,
8. pus.

D. Whereby the test substance is selected from:

- p. tissue,
- q. feces.

E. Whereby the method of observing by instrumental means is selected from

- x. light microscope,
- y. UV spectrophotometer,
- z. laser scanner.

F. Whereby the histochemical reagent

G. Whereby the kit contains:

- i. one component which is one or more antibiotics:
 - a. one antibiotic
 - b. more than one antibiotic;
- ii. two components in addition to above i and a growth medium;
 - a. one antibiotic
 - b. more than one antibiotic;

- iii. two components in addition to above i and a fixing agent;
 - a. one antibiotic
 - b. more than one antibiotic;
- iv. three components or more which includes i. ii, and iii.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 17 and 18 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

Art Unit: 1651

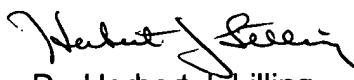
case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined I, II, III or IV and an election of one species from each of the above species as noted in even though the requirement be traversed (37 CFR 1.143).

6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is (703) 308-2034 and fax number is (703) 308-4242 or SPE Michael Wityshyn whose telephone number is (703) 308-4743. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

H.J.Lilling: HJL
(703) 308-2034
Art Unit 1651
July 07, 2002


Dr. Herbert J. Lilling
Primary Examiner
Group 1600 Art Unit 1651